

**SAFETY and EFFECTIVENESS
SUMMARY**

Ideas for Medicine, Inc.
Ideas Dual Port
510(k) Notification

X 962751

PROPRIETARY NAME

Ideas Dual Port

SEP 30 1996

COMMON/USUAL NAME

Venous Access Port

CLASSIFICATION

Class II

CLASSIFICATION NUMBER

80 LJT

DEVICE DESCRIPTION

The Ideas' Dual Port is a totally implantable system designed to provide repeated access to the vascular system. The Ideas' Port allows for the infusion of medications, total parenteral nutrition, blood products, imaging solution, as well as, venous blood sampling. Port access is performed by percutaneous needle insertion using a "Huber type" non-coring needle. The system includes an injection portal with self sealing septum, compression lock and Tecoflex[®] catheter.

SUBSTANTIAL EQUIVALENCE

The Ideas Dual Port is substantially equivalent in its intended use to other (Life Port and Vital Port) marketed dual ports: - to provide chronic venous access. The separate chamber allows for intermittent infusion therapy and/or blood sampling. Its' size, dimensions and geometry are comparable to other ports. Materials are identical to other Ideas Ports except the portal outlet, which is a different grade titanium from the one used in other Ideas Ports. The material, however, is fully biocompatibility. It meets or surpasses the performance specifications in the guidelines on competitive ports and has superior tensile strength at the junction of the catheter and port.